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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/974,584	11/19/1997	THOMAS R. CECH	015389-00295	8401

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EXAMINER

MYERS, CARLA J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/974,584	Applicant(s) CECH ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119 and 127 is/are pending in the application.
- 4a) Of the above claim(s) 127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendments filed June 23, 2005 and September 8, 2005. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

It is noted that the response states that "upon establishing that claim 119 is free of prior art, then claim 127 will also be free of prior art. For this reason, it is requested that claim 127 be rejoined with the group under examination, in accordance with MPEP § 821.04." However, as set forth in MPEP 821.04, the process claims may be rejoined with the product claims upon the determination that a product claim is allowable: "Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained." In the present situation, the elected product has not been found to be allowable. Accordingly, claim 127 is withdrawn from consideration as being drawn to a non-elected invention.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 119 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4 and 7-10 of U.S. Patent No. 6,261,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn generically to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein and the claims of '836 are drawn to a polynucleotide encoding a specific telomerase protein such that the genus of polynucleotides set forth in the present claims encompasses the species set forth in the claims of '836. In particular, the present claims are drawn to a polynucleotide encoding a TRT protein wherein the protein contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. The claims of '836 are drawn to polynucleotides encoding a telomerase protein wherein the polynucleotide hybridizes under stringent conditions to SEQ ID NO: 224 and to variants and fragments thereof. The polynucleotides of SEQ ID NO: 224 encode for a protein having the motifs of present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides claimed in '836 are encompassed by the presently claimed polynucleotides encoding any TRT.

RESPONSE TO ARGUMENTS:

In the response, Applicants state that they will file a terminal disclaimer. A terminal disclaimer has not yet been received by the Office. Accordingly, the rejection is maintained and made final for the reasons stated above.

3. Claim 119 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,767,719.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The present claims are drawn broadly to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein that comprises a sequence having 60% identity with an amino acid sequence of SEQ ID NO: 118 (human TRT) and which comprises conserved motifs a-f as defined in claim 119. As broadly written, the present claims are inclusive of the polynucleotides claimed in '719 which encode for a protein having 90% identity with the mouse TRT sequence of SEQ ID NO: 2 and include the conserved motifs T, 1, 2 and A-D, as defined in '719. The protein of SEQ ID NO: 2 includes the motifs of a-f and comprises an amino acid sequence having at least 60% identity with a portion of SEQ ID NO: 118. Accordingly, the polynucleotides claimed in '719 anticipate the claimed polynucleotides encoding a TRT.

RESPONSE TO ARGUMENTS:

In the response, Applicants traverse this rejection by stating that the mouse TRT polynucleotides of the '719 patent are "not an obvious variant of the claimed polynucleotides." This argument has been fully considered but is not persuasive. The present claims are drawn to a broad genus of TRT polynucleotides. The mouse TRT polynucleotide claimed in the '719 patent falls within the scope of the presently claimed

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genus of polynucleotides. The mouse TRT polynucleotides claimed in '719 meet each of the structural and functional limitations set forth in the present claims. In particular, the claimed mouse polynucleotide (e.g., the mouse polynucleotide encoding SEQ ID NO: 2) is at least 60% identical to present SEQ ID NO: 118 and contains each of the motifs of SEQ ID NO: 139, 143, 144, 146, 147 and 16 / 17. Thereby, the mouse TRT polynucleotides claimed in the '719 patent constitute a species of the presently claimed genus of polynucleotides.

Applicants further traverse this rejection by stating that they "could not have prosecuted the claims in a single application because they are separately owned" and that "(b)oth applications were diligently prosecuted and concurrently prosecuted." However, as stated in MPEP 804, "if the application at issue is the later filed application or both are filed on the same day, only a one-way determination of obviousness is needed in resolving the issue of double patenting." Thereby, Applicants comments regarding the two-way test of obviousness double patenting do not apply to the present situation in which the current application and the '719 patent were filed on the same day. Further, it is noted that MPEP 804 also states that, "(i)f the patent is the later filed application, the question of whether the timewise extension of the right to exclude granted by a patent is justified or unjustified must be addressed. A two-way test is to be applied only when the applicant could not have filed the claims in a single application and there is administrative delay.... Unless the record clearly shows administrative delay by the Office and that applicant could not have avoided filing separate applications, the examiner may use the one-way obviousness determination and shift

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the burden to applicant to show why a two-way obviousness determination is required.”

In the present situation, Applicants have not clearly established that there was an administrative delay.

Lastly, Applicants state that issuance of a patent from the present application would not extend the patent term beyond the expiration of the '719 patent. However, the date of which the patents will expire is not the criteria used to determine the appropriateness of an obviousness-type double patenting rejection. Applicants attention is drawn to the Official Gazette, 1202 OG 112-113, September 30, 1997.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 119 is rejected under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,093,809).

It is noted that the claims are entitled to the present filing date of 11/19/1997. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). The applications to which priority is claimed do not provide basis for the presently claimed subject matter of a genus of polynucleotides encoding a protein having telomerase catalytic activity wherein the proteins comprise each of the structures of the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Additionally, it is pointed out that the inventorship of the '809 patent is distinct from that of the present application. Further, while the record indicates that the present application was assigned to the University of Technology Corporation and Geron Corporation as of 07/17/1997, there is no evidence on the record to establish common ownership at the time the invention was made.

Cech et al teach isolated polynucleotides encoding telomerase reverse transcriptase proteins (TRT) and specifically teaches polynucleotides encoding human telomerase and having the sequence of SEQ ID NO: 118. The human TRT proteins of Cech contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides disclosed by Cech anticipate the claimed invention.

RESPONSE TO ARGUMENTS:

In the response, Applicants traversed this rejection by stating that SEQ ID NO: 118 is the human TRT sequence and that this sequence is disclosed in 6,309,867 and 6,093,809. Applicants further state that "the disclosure of human TRT in U.S. Pat. No. 6,093,809 and U.S. Pat No. 6,309,867 is not 'by another' as required by 102(e).

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Applicants arguments have been fully considered but are not persuasive.

A claim as a whole is granted a date of priority, rather than the individual components of the claim. While the '809 and '836 patents disclose SEQ ID NO: 118, these patents do not disclose the full subject matter of claim 119 and particularly do not disclose the concept of the presently claimed genus of any nucleic acid encoding a protein having 60% with an amino acid sequence of SEQ ID NO: 118 and comprising the sequences of SEQ ID NO: 16/17, 139, 143, 144, 146 and 147 in the order set forth therein. Thereby, claim 119 is not entitled to the filing dates of the '809 and '867 patents. Further, these patents do in fact constitute art "by another" because the inventorship of the present application is distinct from that of the '809 and '867 patents. The inventorship of the '809 and '867 patents is T. R. Cech and T. Nakamura, whereas the inventorship of the present application is T.R. Cech, T. Nakamura, J. Lingner, K.B. Chapman, G.B. Morin, C.B. Harley and W.H. Andrews. Accordingly, the '809 and '867 patents meet the requirements of 102(e) in that they constitute prior art "by another."

5. Claim 119 is rejected under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,309,867).

It is noted that the claims are entitled to the present filing date of 11/19/1997. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). The applications to which priority is claimed do not provide basis for the presently claimed subject matter of a genus of polynucleotides encoding a protein having telomerase catalytic activity wherein the proteins comprise each of the structures of the motifs set

forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Additionally, it is pointed out that the inventorship of the '809 patent is distinct from that of the present application. Additionally, while the record indicates that the present application was assigned to the University of Technology Corporation and Geron Corporation as of 07/17/1997, there is no evidence on the record to establish common ownership at the time the invention was made.

Cech et al teach isolated polynucleotides encoding telomerase reverse transcriptase proteins (TRT) and specifically teaches polynucleotides encoding human telomerase and having the sequence of present SEQ ID NO: 118. Each of these TRT proteins contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides disclosed by Cech anticipate the claimed invention.

RESPONSE TO ARGUMENTS:

In the response, Applicants traverse this rejection for the reasons stated above. Accordingly, the response to those arguments as set forth above apply equally to the present grounds of rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

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The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
November 21, 2005


CARLA J. MYERS
PRIMARY EXAMINER